REMARKS

Claims 1-7 are pending. Applicant notes that the Office Action indicates that claims 1-10 were pending and examined. In a telephone conference with the Examiner on June 5, 2007, the Examiner verified with the undersigned that claims 1-7 are pending and that the alleged obviousness rejection discussed below is directed to claims 1-7, not claims 1-10. Applicant has amended claim 1 to recite "wherein the pharmaceutical composition is a sustained release composition comprising a sustained release pharmaceutical carrier and wherein the release rate of the active ingredient from the composition is from about 4 percent per hour to about 50 percent per hour." Applicant has canceled claims 5-7 without prejudice or disclaimer of the subject matter of those claims. Applicant has also added new claims 8-13. The specification supports these claim amendments and new claims at, for example, page 19, lines 19-26; page 24, lines 10-21; page 30, lines 14-21; and page 31, lines 8-14. Thus, no new matter has been added.

Regarding Applicant's claim to priority to Japanese patent application 2004-292611, the Examiner has not indicated whether this claim to priority has been acknowledged. Accordingly, Applicant requests clarification of the status of the claim to priority.

The Examiner rejects claims 1-7 under one or more of 35 U.S.C. §§ 102(b) and 103(a). Applicant addresses these rejections below.

Rejections Under 35 U.S.C. § 102(b)

Claims 1-4 and 7 are rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Suzuki et al. (*J. Pharmacol. Exp. Ther.* 275:728-36 (1995); "*Suzuki*"). According to the Examiner, Suzuki teaches the effects of (-)-S-2,8-dimethyl-3-methylele-1-oxa-8-

azaspiro[4,5]decane L-tartrate monohydrate (YM796) on the disturbance of passive avoidance learning behavior in drug-treated and senescence-accelerated mice. (Office Action, p. 2.) *Suzuki* allegedly discloses that the compound is a novel muscarinic agonist and has an effect on the disturbance of passive avoidance learning behavior in drug-treated mice. (*Id.*) The Examiner also contends that muscarinic action of the autonomic nervous system is well known, referring to an article by Martin and Lobert (*Crit. Care Nurse* 23:15-20 (2003); available at http://cnn.aacnjournals.org/cgi/content/full/23/5/15; "*Martin*"). (*Id.*) One of these muscarinic activities allegedly includes a drying effect on the eyes and mouth. (*Id.*) The Examiner also suggests that the effects of the drug and its mechanism of action, as recited in claims 3 and 4, are inherent properties of the drug. (*Id.*) Applicant traverses with regard to claims 1-4, which are still pending.

Solely to facilitate prosecution and without acquiescing in the rejection, Applicant amended claim 1 to recite "a sustained release composition . . . wherein the release rate of the active ingredient from the composition is from about 4 percent per hour to about 50 percent per hour." *Suzuki* does not teach a "sustained release composition," let alone a composition in which "the release rate of the active ingredient from the composition is from about 4 percent per hour to about 50 percent per hour." Because *Suzuki* fails to teach all the elements of independent claim 1, this reference cannot anticipate claim 1 or dependent claims 2-4. Applicant requests that the Examiner withdraw this rejection.

The Examiner rejects claims 1, 2, and 7 under 35 U.S.C. § 102(b) as allegedly anticipated by Shin-Ichi et al. (WO 92/20683; "*Shin*"). The Examiner alleges that *Shin*

teaches the compound (-)-S-2,8-dimethyl-3-methylele-1-oxa-8-azaspiro[4,5]decane L-tartrate that has a storage stability superior to that of other salts, is applicable as a medicine, and has selective affinity for the muscarinic acetylcholine receptor. (Office Action, p.3.) According to the Examiner, the phrase "treatment of tear and salivary fluid drying" as recited in claim 1 is the intent of use and is not given patentable weight. (*Id.*) The Examiner also contends that it is within the muscarinic agonist effect of the compound to enhance the secretion of lacrimal and salivary glands. (*Id.*) Applicant traverses with regard to claims 1 and 2, which are still pending.

As discussed above, Applicant amended claim 1 to recite "a sustained release composition . . . wherein the release rate of the active ingredient from the composition is from about 4 percent per hour to about 50 percent per hour." Like *Suzuki*, *Shin* does not teach a "sustained release composition," let alone a composition in which "the release rate of the active ingredient from the composition is from about 4 percent per hour to about 50 percent per hour." Because *Shin* fails to teach all the elements of independent claim 1, this reference cannot anticipate claim 1 or dependent claim 2. Accordingly, Applicant requests that the Examiner withdraw this rejection.

Claims 1 and 3-7 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Brann et al. (U.S. Patent 6,528,529; "*Brann*"). (*Id.*) *Brann* allegedly teaches compounds that are the same as those recited in the instant application and teaches sustained release preparations. (*Id.*) Brann also allegedly teaches several dosage forms. The Examiner suggests that all of the dosage forms usually include carriers. (*Id.*) Applicant traverses with regard to claims 1, 3, and 4, which are still pending.

As discussed above, Applicant amended claim 1 to recite a composition "wherein the release rate of the active ingredient from the composition is from about 4 percent per hour to about 50 percent per hour." *Brann* does not teach a composition in which "the release rate of the active ingredient from the composition is from about 4 percent per hour to about 50 percent per hour." Because *Brann* fails to teach all the elements of independent claim 1, this reference cannot anticipate claim 1 or dependent claims 3 and 4. Accordingly, Applicant requests that the Examiner withdraw this rejection.

Rejection Under 35 U.S.C. § 103(a)

The Examiner rejects claims 1-7 under 35 U.S.C. § 103(a) as allegedly obvious over *Brann* in view of *Suzuki* or *Shin*. The Examiner applies *Brann* as discussed above and acknowledges that *Brann* does not disclose the tartrate salt of the claimed compound. (Office Action, p. 4.) *Suzuki* and *Shin* allegedly disclose the use of the L-tartrate form as recited in claim 2. (*Id.*) Based on these alleged teachings, the Examiner concludes that it would have been obvious to produce 2,8-dimethyl-3-methylele-1-oxa-8-azaspiro[4.5]decane in a sustained-release form to prolong the action of the compound on lacrimal and salivary glands and produce it tartrate salt because this form allegedly has a superior storage stability. (*Id.*) Applicant respectfully traverses with regard to claims 1-4, which are still pending.

As noted above, neither *Brann*, *Suzuki*, nor *Shin* teach a composition "wherein the release rate of the active ingredient from the composition is from about 4 percent per hour to about 50 percent per hour" as recited in independent claim 1. Because this element is missing from all three references, they cannot render claims 1-4 obvious when taken alone or in combination. For one of ordinary skill in the art to arrive at the

composition of claim 1 in light of these reference, he would have to improperly use hindsight based on the specification's disclosure. Applicant therefore respectfully requests that the Examiner withdraw this rejection.

Conclusions

In view of the foregoing amendments and remarks, Applicant respectfully requests reconsideration and reexamination of this application and the timely allowance of pending claims 1-4 and 8-13.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account 06-0916.

Respectfully submitted,

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Dated: July 31, 2007

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